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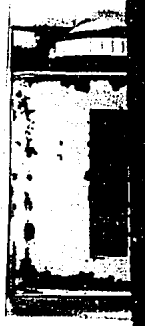


USSR WORK ON ANTITULAREMIA VACCINATION PROCEDURES

[Comment: This report presents the complete text of the article "A Contribution to the History of Antitularemia Vaccination," published by V. S. Sil'chenko of the Voronezh Oblast Antitularemia Station in Zhurnal Mikrobiologii, Epidemiologii, i Immunobiologii, No 10, October 1955, pp 83-89.]

The outstanding Soviet scientist, N. A. Gayskiy, whose 70th anniversary has been celebrated recently and to whose memory this paper is dedicated, started his activity at an early age. He participated in antiplague work as a third-year student. Subsequently, Gayskiy spent many years in work on plague.

A particularly outstanding achievement of Gayskiy was the development of a live tularemia vaccine, a preparation which is very effective in antiepidemic work.

Work on the development of tularemia vaccines was initiated in the USSR in 1931 by Khatenever in collaboration with Levchenko and Sinay. These workers prepared a glycerine vaccine from killed tularemia baccilli. Later, Khatenever subjected to investigation a heated vaccine, a formalin vaccine, and a quinosol vaccine. The experiments were carried out on guinea pigs. According to Khatenever's data, the quinosol vaccine proved to be more effective than the others which had been subjected to tests.

In 1931, Khatenever for the first time in the world carried out a vaccination of human beings against tularemia. Forty-one persons were injected on that occasion with the glycerine vaccine. Unfortunately, the vaccinated persons were kept under observation for 3 weeks only.

In 1934, Miller and Grzhebina started an investigation of tularemia vaccines. They immunized rabbits, susliks, and white mice with live and killed agar and glycerine vaccines. However, on subsequent infection the majority of the vaccinated animals died of tularemia.

In 1935, Sinay investigated the protective quality of heated glycerine vaccine on white mice. However, neither a single nor a quadruple immunization protected the animals from death.

In 1936, Khatenever and Levchenko prepared a vaccine from live cultures of low virulence and a polyvalent vaccine from killed cultures of B. tularense. The vaccine derived from live strains of low virulence did not yield good results and the majority of the experimental animals treated with this vaccine died on subsequent infection. In Khatenever's opinion, the polyvalent vaccine yielded better results.

In 1937, Miller and Grzhebina reported on the experimental application of local immunization against tularemia, i.e., cutaneous inoculation. For this purpose, they used cultures subjected to partial lysis and also soda and aqueous antigens. These investigators arrived at the conclusion that immunization of animals by the cutaneous method apparently enhances the resistance of the organism.

Khatenever, and later Burgasov who worked under Khatenever's direction, immunized rabbits with an extract prepared at an elevated temperature (thermal extract). According to Khatenever, the majority of the rabbits immunized by this method survived.

Attempts have been made to use the sera of immunized animals but, according to the data obtained by Miller and Grzhebina, these sera exerted only a weak prophylactic effect.

Simultaneously with the investigation of killed tularemia vaccines, a small number of human beings were inoculated with these vaccines. Although Grzhebina had vaccinated 46 trappers of water rats [Arvicola terrestris], with the formalinized vaccine 22 of the trappers succumbed to tularemia soon afterwards. Khatenever, together with Tsvetkova and Gorbunova, vaccinated with the polyvalent vaccine nine workers at the tularemia laboratory, but the result was rather unsatisfactory in this case as well, because four of them got tularemia soon afterwards. Khatenever obtained relatively good results with the application of killed tularemia vaccine only in one case. In 1944, 598 persons were treated with this vaccine in the Tyumen' Oblast and none of them caught tularemia during the 4-5 months subsequent to the inoculation.

Work on the development of tularemia vaccines has also been conducted abroad. E. Francis in the US investigated formol and phenol vaccines. He also used for immunization sublethal doses of a virulent tularemia culture and vaccines derived from nonvirulent cultures. The experiments carried out by Francis along these lines did not yield good results. He also did not get any positive results in connection with the application of filtrates from virulent cultures.

Aoki, Kondo, and Tuzawa (Japan, 1927-1928) immunized rabbits and guinea pigs with a suspension of the brain of animals which had died of Ohara's disease (tularemia). This suspension had been heated at 60 degrees during 15 minutes prior to application. According to the data published by these investigators, the results obtained by them were good.

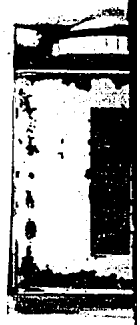
M. Kudo (Japan, 1930 and 1934) used heated phenol and formalin vaccines for inoculations. He noted that white mice and guinea pigs which had been inoculated survived, following infection with B. tularense. He also prepared a vaccine from a virulent strain. Downs (1932) prepared a vaccine by adding 0.2 percent of formalin to a suspension of bacteria in physiological salt solution. The vaccination was carried out six or eight times. The animals that had been inoculated survived, but were sick for periods up to 90 days.

Oz and Talaf Vasfi (Turkey, 1940) immunized animals with antitoxin that had been rendered harmless.

E. Gotschlich, Galem, Said Bilal, and Tansin Berkin (Turkey, 1940) used vaccines prepared from live attenuated tularemia strains. In their experiments more than one third of the immunized guinea pigs died of the action of endotoxin and almost half of the mice died of the tularemia (infection) process, while the remaining animals survived subsequent infection.

L. Foshay, W. H. Hesselbrock, H. J. Wittenberg, and A. H. Rodenberg (US, 1942) prepared a vaccine from a virulent strain of B. tularense which had been treated with an aqueous solution of sodium nitrite and acetic acid. Although this vaccine is considered to be one of the most effective in the US, it does not produce in the inoculated subjects a lasting and intensive immunity. According to Foshay's data, the vaccine does not protect the inoculated subjects fully from infection.

T. J. Kadull, H. R. Reames, L. L. Coriell, and L. Foshay (US, 1950) used phenol and acetone extracts from a virulent strain of B. tularense. However, the vaccines of this type also proved to be rather ineffective, because one third of those inoculated with them acquired tularemia.



After analyzing the data on antitularemia vaccinations published in the USSR and abroad, we are forced to the conclusion that vaccines prepared from killed culture of B. tularense have proved to be rather ineffective. Although their use required multiple vaccinations (up to eight times), it nevertheless created in those inoculated only a short-lived immunity of insufficient intensity.

When vaccines derived from live cultures had been prepared and used, unsatisfactory results were also obtained originally.

The reason was that the investigators apparently did not yet have at their disposal strains with a sufficiently weakened virulence and a high enough immunogenicity.

The problems inherent in the specific prophylaxis of tularemia were brilliantly solved by Gayskiy, who, beginning with 1935 and working in collaboration with B. Ya. El'bert, has conducted work on immunity to tularemia. He discovered a repository strain of B. tularense which had a weakened virulence but very high immunogenetic characteristics (the strain "Moskva," i.e., Moscow). This strain was tested on 10 volunteers and proved to be completely harmless. At the same time, it produced an allergic rebuilding of the organism and induced development of antibodies in those inoculated. This strain was lost later and Gayskiy succeeded in 1944 only after considerable effort in obtaining new [suitable] strains of B. tularense according to a special method he developed. One of the attenuated strains, which was nonvirulent to guinea pigs and relatively virulent to white mice, was called by Gayskiy "Bowillon Strain No 15." A second strain of this type was named "Ondatra [Muskrat] IV Strain."

Subsequently successful work on the modification of the natural properties of B. tularense and the preparation of vaccine strains was carried out by Faybich, Mayskiy, Yelmel'yanova, and others.

Gayskiy used his attenuated strains for the preparation of live tularemia vaccines. The work in question was carried out at the Irkutsk Antiplague Institute. In the first half of 1942, the first batch of liquid live antitularemia vaccine for subcutaneous application (called "virus vaccine" by Gayskiy) was produced.

Although the vaccine proved to be innocuous in animal experiments, it had to be checked on human beings before being released for general use. Workers at the Irkutsk Antiplague Institute expressed willingness to have the vaccine tested on them. Furthermore, some of these workers agreed that a control infection with a virulent tularemia culture be carried out on them subsequent to the test vaccination. On 2 June 1942, 50 persons were inoculated for the first time with a live antitularemia vaccine. At the end of 1942, six of these persons were subjected to an experimental infection with a virulent tularemia culture. Gayskiy, in his work "The Tularemia Virus-Vaccine," stated "The workers at out institute without hesitation volunteered for a control infection with a virulent culture to be carried out on themselves," and further stated that the persons who volunteered for this test were N. D. Altareva, A. V. Korotkova, Ye P. Makarova, A. G. Lopotukhina, V. N. Rychkova, V. Ya. Mikhaleva, T. G. Linnik, Glad'ko, A. M. Teichkina, and Z. Kravchenko.

The test described fully confirmed the experimental data obtained earlier on animals and proved the harmlessness of the vaccine as well as its high protective effectiveness. At the end of 1942, 1,300 persons had already been inoculated in the Kirov Oblast under Gayskiy's direction. In 1943, 2,214 persons were inoculated in the Voronezh Oblast and 2,000 persons in Kazakhstan. This was the first attempt at the mass vaccination of human beings against tularemia with a live antitularemia vaccine.

Gayskiy's vaccine, although effective as an antiepidemic prophylactic agent, had a substantial drawback: it rapidly lost its immunogenic properties (within 7 days at room temperature). This made the transportation of the vaccine and its use in remote regions, particularly during the summer, rather difficult.

In 1944, Gayskiy, in collaboration with Golinevich, developed a dry antitularemia vaccine. Gayskiy found that when kept at zero to 2 degrees this vaccine preserves its immunogenic properties during 5 months. In Gayskiy's opinion, this is not the maximum time during which the vaccine may retain its effectiveness. However, the work on the dry vaccine was not completed by Gayskiy. In 1943, Gayskiy received the degree of doctor of medical sciences for his work, "The Preparation of the Tularemia Virus-Vaccine and the Checking of Its Immunogenic Properties." In 1946, Gayskiy jointly with El'bert was given a Stalin Prize for work on the development of the live antitularemia vaccine.

Faybich continued Gaskiy's work on the development of the live tularemia vaccine. He applied the method of drying in a high vacuum (with the use of a special medium) of a frozen suspension of tularemia bacilli constituting the live vaccine. This work was carried out according to the method proposed by Faybich in equipment developed by the following workers at the [Scientific Research] Institute of Epidemiology and Hygiene of the Red Army (NIIEG); Karneyev, Del'nik, Grudenkov, and Chernykh.

Faybich and Tamarina prepared a live dry tularemia vaccine for subcutaneous vaccination and, subsequently, one for cutaneous vaccination. This vaccine could be kept at low temperatures up to 2 years without a loss of immunogenic properties. In the preparation of the dry vaccine, a precise dosage of the quantity of bacterial cells in the preparation could be carried out, which is something that could not be accomplished in the preparation of the liquid vaccine. These valuable properties of the dry vaccine contributed to the fact that it is considered at present the best available live tularemia vaccine.

In 1945, El'bert proposed a cutaneous method of antitularemia vaccination. He, together with Tinker, Pushkova, and others, prepared a live liquid tularemia vaccine, using Drozhevkina's yolk medium. The cutaneous method of vaccination makes it possible to immunize a large number of persons within a short time.

The fact that 10 years have passed since the initiation of mass vaccination of human beings against tularemia and the circumstance that a great number of persons has been vaccinated since then have enabled Soviet scientists to make valuable observations with the purpose of determining the effectiveness of the vaccination procedure. We are of the opinion that a point has been reached at which the data that have been accumulated must be summarized. A summary of the results is also necessary for the reason that occasionally contradictory information is published as far as the duration of immunity after vaccination, the time during which immunological reactions are preserved in those inoculated, and the period after which revaccination is necessary are concerned. Vaccination with the liquid yolk vaccine proposed by El'bert took well in 100 percent of the cases under experimental conditions. When this vaccine was used under practical conditions, the percentage of cases in which the vaccination took well varied between 90-95 percent (Tsareva and Sil'chenko) and 63-64 percent (Dem'yanov).

The low percentage mentioned must be regarded as due to violation of rules in regard to the storage of the vaccine and use of an improper technique of vaccination. The lowest percentage was observed when the vaccine was used close to the limiting time at which the maximum period of its effectiveness expired. When stored for the same period of time, the dry tularemia vaccine gives a higher percentage of successful vaccination than the liquid vaccine.

According to a figure arrived at by Olsuf'yev, who used a great number of observations, the percentage of cases in which vaccination with a dry vaccine takes well reaches 97 percent on the average. The change to the production of dry antitularemia vaccine at the institutes must be regarded as justified.

The application of the cutaneous method of vaccination simplified determination of the percentage of cases in which the vaccination takes because a skin reaction develops in those vaccinated when this method is used. Originally a check as to whether the vaccination took well was carried out on the fourth or fifth day after the vaccination. Observations carried out subsequently by Myasnikov, Sil'chenko, Tsareva, and others have shown the visible reactions in a part of the persons vaccinated may appear even after the 10th day, so that a check must be made during the 12th-15th day period. Carrying out the check at this time eliminates errors in conclusions as to whether the vaccination has taken well or not. Shmuter states that he has observed reactions on the 20th day and subsequent to the 20th day. However, appearance of the reaction at a date as late as this occurs very rarely and for that reason should not be taken into consideration from the practical standpoint.

In connection with the initial application of the live vaccine, Kosmachevskiy observed in a considerable number of cases pronounced reactions, i.e., a temperature rise in 50 percent of the cases, enlargement of lymphatic nodes in 30 percent of the cases, etc. Gayskiy and Khizhinskaya observed reactions in 20-30 percent of those vaccinated. Further observations carried out by Gayskiy, Uglova, Zhatkovskiy, Sil'chenko, and others demonstrated that in the majority of those vaccinated the vaccination does not produce any side effects. Whenever a reaction to the vaccination takes place, it is most often expressed in subjective complaints including headaches, weakness, and a general feeling of illness. These reactions appear on the second to third day after the vaccination. They continue from several hours to one day and then disappear completely. As far as more pronounced reactions are concerned, one may note occurrence of a raised temperature and of a swelling of the under-arm (regional) lymphatic nodes. These pronounced reactions are found in persons who have heightened reactivity. They also appear in cases when an unusually large quantity of vaccine has been administered. Tests carried out on a mass scale have confirmed the complete harmlessness of live tularemia vaccines and their low tendency to produce reactions.

Observations carried out by Gayskiy, El'bert, Khatenever, Faybich, Mayskiy, and others have shown that both in persons who have been vaccinated and in persons who have recovered from tularemia an immunobiological reconstruction of the organism takes place, as a result of which a state of allergy develops and formation of antibodies occurs. Gayskiy and El'bert are of the opinion that allergy in tularemia is one of the significant indices of immunity. For this reason they recommend that the retention of the allergic reaction by persons who have been vaccinated should be regarded as a sign that immunity still exists. The allergic reaction in the persons who have been vaccinated appears 5-15 days after vaccination and subsequently is preserved for a long time measured in years. Tsareva and Myasnikov determined that there is a positive allergic reaction in 100 percent of the persons vaccinated

after 4 — 4 1/2 years, while Altareva observed this reaction after a period of 6 — 6 1/2 years and Miroshnichenko, after 7 years. Our latest observations have shown that this reaction is preserved in a considerable proportion of those vaccinated even after the expiration of 8 years.

Some investigators noted that there is rapid disappearance of the allergic reaction in vaccinated persons. Chernina stated that the reaction disappears after 15 months and Bondar', Anina-Radchenko, and Tatko even stated that the reaction disappears 10 months after the vaccination. These data, which are not in agreement with those obtained by the majority of investigators, can be explained only by the fact that the vaccinations were carried out with a vaccine that had lost its capacity to produce immunity. Some investigators do not take into consideration the fact that in persons who had been vaccinated the allergic reaction to tularin develops much later than in persons who have recovered from the disease (i.e., at the expiration of 48 hours). By checking the allergic reaction at an earlier time, they get erroneous results.

The agglutinins in the blood of vaccinated persons are determined by establishing the diagnostic titer 2-4 weeks after vaccination. The disappearance of agglutinins in vaccinated persons takes place at an earlier time than the disappearance of the allergic reaction. According to Yudenich's data, agglutinins are absent in 70 percent of vaccinated persons after one year and in 39 percent after 3 years. According to our data, agglutinins were not found in 49 percent of vaccinated persons after 5 years, while the allergic reaction was absent only in 11.1 percent of these persons.

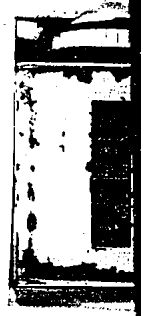
The opsono-phagocytic reaction in vaccinated persons was determined by Gayskiy, Zav'yalova, Altareva, and Khanin. It is true that these investigations were carried out on only a small number of vaccinated persons. Nevertheless, Gayskiy and his collaborators established that the reaction in question appears in vaccinated persons already at the expiration of 3 days and persists for 2-3 years, while Altareva found that the reaction was still present in vaccinated persons at the expiration of 6 years.

The persistence of immunological reactions in vaccinated persons, above all the allergic reactions, makes it possible to use these reactions extensively for the determination of the presence of immunity to those vaccinated. El'bert and his collaborators noted that, subsequent to vaccination, there were no cases of tularemia among the persons vaccinated, while 4.3 percent of those who had not been vaccinated caught tularemia. Similar data were obtained by Mayskiy, Olsuf'yev, Selezneva, Borodin, and others.

Beginning with 1946, live antitularemia vaccine has been used extensively in practical antiepidemic work as soon as initial infections with tularemia appeared. The result obtained was invariably good. The occurrence of human infections stopped 10-15 days after the vaccinations had been carried out. The success of the prophylactic measures taken is certain when the vaccinations are carried out rapidly (within 3-5 days) and the whole population is vaccinated in the region where the disease appears.

The live tularemia vaccine in the dry or liquid state proved to be an excellent prophylactic preparation which protects with certainty from the disease whenever the vaccination is carried out at the very moment when the outbreak of tularemia flares up.

Experience has shown that persons who have been vaccinated are protected for a long time against infection with tularemia even when they work with material which is known to be infected, e. g., material handled in laboratories. This induced us to propose that prophylactic vaccinations be administered to persons who are exposed to the danger of infection (persons who live in the



vicinity of natural reservoirs of tularemia, workers in antitularemia institutions, hunters of water rats and muskrats etc.) Observations carried out during 5-6 years have shown that no member of the group that had been vaccinated caught the disease during this time, while persons who had not been vaccinated and did the same type of work in the same locality, were infected with tularemia. These results confirmed that it is advisable to carry out prophylactic vaccination of human beings. At present, according to a statement made by Olsuf'yev, the method of prophylactic vaccination is universally applied.

El'bert, Tinker, Puchkova, and others noted that infection with tularemia among persons vaccinated with live vaccines occurs only between the second and tenth day after vaccination. According to Borodin's observations, only three persons caught the disease one month after vaccination.

He established that the incidence of infection among persons vaccinated generally drops during the first week in 77.3 percent of the cases. After the 16th day following the vaccination, cases of the disease among the vaccinated are not observed. It follows that the vaccinated persons catch the disease only during the period when they have not yet developed a sufficiently intensive immunity. Thus, the live antitularemia vaccine has successfully passed the basic test of its quality, because incidences of the disease among the vaccinated at remote periods after the vaccination (after 6 years) have not been found to occur. It is necessary to note in this connection that in foreign countries not a single vaccine that is being applied protects the persons vaccinated against tularemia even for a short time after vaccination. In determining whether postvaccination immunity has been established it is necessary to consider epidemiological data in their interrelationship with the preservation of the allergic reaction by the persons vaccinated. Gayskiy, El'bert, Faybich, Mayskiy, and Olsuf'yev were of the opinion that immunity after vaccination with live tularemia vaccines is preserved for approximately 4 years, i. e. the period during which the persons vaccinated had been subjected to observation. Observations carried out during recent years testify to the fact that the period during which intensive immunity is retained by the persons vaccinated (taking into consideration that the allergic reaction persists for 5-6 years and that there are no cases of infection during this period) equals 5-6 years and may be longer in some cases.

One cannot agree with Chernina, who speaks of an immunity that continues for 6 months, or Kazberyuk's opinion to the effect that the duration of immunity is 2-3 years, or the view expressed by Bondar', Anina-Radchenko, and Tatko, who stated that lowering of the immunity takes place already 10 months after the vaccination.

Introduction of antitularemia vaccination into the general public health practice necessitated a solution of the problem as to when revaccinations must be carried out. Faybich suggests that revaccinations be carried out every year, according to epidemiological indications, Kazberyuk every 2 years, and Yudenich every 4 years. In our opinion, the problem in regard to the time when revaccination must be carried out depends on the time during which an intensive immunity is retained by the persons vaccinated. In view of the fact that all data (absence of incidences of infection, preservation of immunological reactions, absence of response to the vaccine after revaccination, and persistence of the effect during 5-6 years in the majority of those vaccinated) indicate that an intensive immunity is retained by the majority of those vaccinated up to 6 years, so that there is no reason for revaccinating them within a period shorter than 6 years.

Prolonged observations carried out on vaccinated persons and a study of the immunogenic and antiepidemic properties of live antitularemia vaccines have shown that, thanks to the work done by N. A. Gayskiy, El'bert, and Faybich, Soviet medicine has at its disposal a remarkable preparation which is highly effective and which is not equaled by anything that is available at present in foreign countries.

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